Medtronic

AEX™ Generator

Operator's Manual

REF **40-405-1**

Rx Only

Medtronic

AEX™ Generator

Operator's Manual

REF **40-405-1**

Rx Only

℞ Only

- **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Customer Service Telephone Numbers:

U.S. :
Tel: +1 866 777 9400
Fax: +1 866 222 0900

United Kingdom:
Tel: +44 1923 212213
Fax: +44 1923 241004

France:
Tel: +33 4 7067 9800
Fax: +33 4 7067 9820

Belgium-Luxemburg:
Tel: +32 2 456 0900
Fax: +32 2 460 2667

Canada:
Tel: +1 800 268 5346
Fax: +1 905 826 6620

China:
Tel: +86 21 50800998
Fax: +86 21 50800978/50801850

Germany:
Tel: +49 211 529 3209
Fax: +49 211 529 3302

India:
Tel: +91 22 26836733
Fax: +91 22 26830806

Japan:
Tel: +81 3 6430.2011
Fax: +81 3 6430 7110

Netherlands:
Tel: +31 45 566 8000
Fax: +31 45 566 8042

Contents

List of Tables

1. Preface

About This Manual

The *AEX™ Generator Operator's Manual* provides detailed information on operating and maintaining the AEX™ Generator. This manual and the equipment described within are for use only by qualified medical personnel possessing training in the surgical procedures to be performed.

For information on accessories, refer to the appropriate Instructions For Use. The AEX™ Generator is compatible with all Aquamantys™ and PlasmaBlade™ single use only accessories.

Conventions Used in This Manual

▲ **WARNING:** A warning indicates a hazardous condition that may result in injury or death, if not corrected or avoided.

◆ **CAUTION:** Alerts you to the possibility of a problem with the device associated with its use or misuse resulting in equipment damage or failure in a procedure, if not corrected or avoided.

■ **IMPORTANT:** Highlights important information for a particular section.

● **NOTE:** Points out additional information that may be helpful.

Help

Read through the section of the guide specific to the procedure you are performing. Refer to the table of contents and index to locate information. A glossary is included to assist you with any unfamiliar terms.

1. See Troubleshooting on page 6-1 for a list of problems and suggested solutions.
2. For technical support, contact +1 866 777 9400.

Indications

The AEX™ Generator is a radio frequency (RF) electrosurgical generator capable of simultaneously powering specified monopolar and bipolar electrosurgical instruments. It is intended to be used for delivery of RF energy to instruments indicated for cutting and coagulation of soft tissue and for delivery of RF energy concurrent with saline to instruments indicated for hemostatic sealing and coagulation of soft tissue and bone. It is intended for, but not limited to, General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological, Thoracic, and Open abdominal surgery procedures. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Contraindications

The AEX™ Generator with Aquamantys™, Transcollation™ and PlasmaBlade™ should not be used on small appendages or body parts, as in finger surgery or circumcision.

Warnings and Cautions

Electrosurgery has been used safely in many procedures. Physicians should be familiar with the medical literature, complications, and hazards associated with electrosurgery before beginning any electrosurgical procedure. Electrosurgery, if misused, can pose dangers to patients or staff, as well as other equipment. Safe and effective electrosurgery is dependent not only on equipment design, but also on factors under the control of the user, such as surgical training and clinical decision making. The warnings and cautions presented in this manual should be read, understood and followed for safety purposes.

▲ Warnings for Equipment Preparation

- Connect the Generator electrical cord to a properly grounded Hospital Grade receptacle. Do not use extension cords or three-prong to two-prong adapters with the Generator. Improper grounding may result in equipment damage, fire at the receptacle, or injury to the patient or user.
- **NOTE:** "Use Hospital Grade receptacle for grounding reliability" statement applies to US/North America power cords only.
- To allow for appropriate cooling, the unit should not be installed in a cabinet or similar enclosure. If mounted on a shelf, or near a wall, allow a three-inch clearance around the unit to permit free circulation of air on all sides of the unit. Appropriate cooling is necessary to avoid overheating of the unit.
- Do not stack equipment on top of the AEX™ Generator or place the generator on top of electrical equipment. This may block access to the unit and not allow for proper ventilation.
- Provide as much distance as possible between the AEX™ Generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.
- Prior to use, inspect the AEX™ Generator and its accessories for any obvious defects or improper connections. Do not use the Generator if it appears to be damaged, as product failure or injury may occur.
- Avoid fluid contact with the accessory cable interfaces to the AEX™ Generator receptacles, because shorting can occur which can damage the accessory connectors and/or the AEX™ Generator receptacles.
- Use only AEX™ Compatible Footswitches.
- Do not use cords as handles as insulation damage could occur and increase the risk of burns or cause other injury.
- Do not wrap power cords around metal objects. This may induce currents that could lead to shock, fire, or injury to the patient or surgical team. All power cords should be positioned in a way to avoid contact with the patient or other cables.
- Nonfunction of the AEX™ Generator may cause interruption of surgery. A backup generator or alternative surgical techniques should always be available.
- Interference from high frequency surgical equipment may adversely affect the operation of other electronic medical equipment in the operating room. Interference may be resolved or reduced by rearranging the Generator's cables such that they do not overlap the cables from other equipment, or by using different power outlets or extension cords for the different pieces of equipment.
- Patient monitoring systems that incorporate high-frequency current-limiting devices are recommended for use in an electrosurgical site.

▲ Warnings for Accessories

- Prior to use, inspect all accessory devices, handpieces, and the AEX™ Generator for defects. Do not use if insulation or connectors are damaged, because product failure or injury may occur.
- The AEX™ Generator is compatible with all Aquamantys™ and PlasmaBlade™ handpieces.
- The AEX™ Generator is not compatible with Aquamantys™3 handpieces.
- Do not reuse, resterilize or reprocess "Single Use Only" labeled accessory devices, because product failure or injury may occur.
- The handpieces and Patient Return Electrodes have appropriate connectors and receptacles. Do not attempt to connect to the improper receptacle because connector damage can occur, which may result in a failure. Ensure all connections are secure before activating the system.
- Verify that the Patient Return Electrode is properly applied to the patient and the cable is securely connected to the Patient Return Electrode receptacle. If there is an improper connection the AEX™ Generator may not operate as intended.
- Do not connect wet connectors to the AEX™ Generator as this may result in equipment damage, fire at the receptacle, or injury to the patient or user.
- Do not wrap cords around metal objects as this may induce currents that could produce system performance changes, shocks, fires, or injury to the patient or surgical personnel.
- Do not use accessories other than the ones recommended in Product Accessories. Use of other accessories may result in an unintended output and/or injury to patient.
- Use active accessories with rated voltage equal to or greater than that of the AEX™ Generator's maximum output voltage.

▲ Warnings for Patient Preparation

- Observe fire precautions at all times. An electrosurgical device may provide an ignition source due to sparking and heating.
- Do not use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen. Do not activate the unit until vapors from alcohol-based skin prepping agents have dissipated. Naturally occurring gases that accumulate in body cavities can also be an ignition source.
- Ensure that all oxygen circuit connections and endotracheal tubes are leak-free before and during electrosurgery use. An oxygen leak could result in an airway fire.
- Inadvertent patient contact may result in burns. When not in use, place all accessory devices in a dry and nonconductive area away from the patient.
- Position the cables for a Monopolar handpiece and the Patient Return Electrode to avoid patient contact to protect against high frequency current paths to the patient, as such contact may result in patient or user injury.
- Do not allow patient contact with grounded metal objects or objects that have an appreciable capacitance to earth (e.g., operating table supports), as such contact may result in patient or user injury.
- Skin-to-skin contact (e.g., between the arms and body of the patient) should be avoided, e.g., by insertion of dry gauze.

- Monopolar devices require a Patient Return Electrode. The Generator must detect proper Patient Return Electrode impedance before output can be active. The impedance is continuously monitored and displayed while in Monopolar Mode. The Generator presents audible and visible alarms if it detects improper impedance with the Patient Return Electrode in Monopolar Mode and will disable Generator output. Unless a compatible split foil Patient Return Electrode is used, loss of safe contact between the return electrode and the patient will not result in an audible and visible alarm, and the Generator output will not be disabled. The entire area of the Patient Return Electrode should be reliably attached to a suitably prepared and appropriate area of the patient's body as defined by the manufacturer. Refer to the manufacturer's instructions for application site and placement procedures when applying the Patient Return Electrode. Do not rely entirely on the impedance sensing feature. It can be affected by a damaged (shorted) Patient Return Electrode. It is recommended that the operator verify appropriate placement and contact of the Patient Return Electrode. Inadequate contact of the Patient Return Electrode may result in patient alternate site burns or injury.
- Do not cut a Patient Return Electrode to reduce size as this could result in high current density patient burns.
- Heat applied by thermal blankets or other sources may be cumulative with heat from the Patient Return Electrode (caused by electrosurgical currents). Choose a Patient Return Electrode site remote from other heat sources to help minimize the risk of patient injury.
- Electrodes and probes used with monitoring, stimulating, and imaging devices can provide paths for high frequency currents even if the electrodes or probes are insulated, battery operated, and/or isolated at 50/60 Hz. To reduce the risk of burns, place any such electrode or probe as far away as possible from the electrosurgical site and the Patient Return Electrode.
- Needle monitoring electrodes are not recommended as burns may inadvertently result.
- The active device should not be used near electrocardiograph electrodes as it may cause interference.
- Physiological monitoring devices and their monitoring electrodes should be positioned away from the surgical site where the AEX™ System will be utilized.
- Always use the lowest RF power setting to achieve the desired surgical effect. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the power and the longer the power is applied, the greater the possibility of unintended thermal damage to tissue.
- Adequate ventilation to reduce electrosurgical smoke by use of a smoke-plume evacuator or other means is recommended.
- Do not attempt to alter device configurations or replace device components with nonstandard parts since this may result in decreased device performance, device malfunction, or patient injury.
- Transcollation delivers RF energy in conjunction with saline. Do not inhibit the delivery of saline as burns may inadvertently result.

▲ Warnings for Active Implants

- If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activations of ICDs.
- Use the AEX™ System with caution in the presence of pacemakers or other active implants, as electrosurgical equipment may cause interference with these devices or cause them to malfunction. Consult the active implant manufacturer for further information before proceeding with the surgery.
- The use of electrosurgery in the presence of internal or external active implants is potentially hazardous.
- To minimize the possibility of active implant interference, place the Patient Return Electrode such that the electrosurgical current path is as far as possible from the active implant lead.
- Direct contact with implanted leads can cause physical damage to the leads. Exercise caution around leads associated with any active implant; particularly those with thin insulation.

▲ Warnings for Use

- It is recommended that physicians utilize pre-clinical training, review of pertinent literature, and other appropriate educational tools before attempting newer surgical procedures, such as endoscopic, laparoscopic, or thoracoscopic procedures.
- Read the warnings, precautions, and instructions provided with AEX™ disposable handpieces before using. Specific instructions are not included in this manual.
- If using the optional footswitch, ensure that the footswitch is not inadvertently depressed to prevent the device from being unintentionally activated. Place the footswitch in a location necessitating deliberate action in order to activate the unit.
- If using the optional footswitch, only the primary surgeon using the handpiece should operate the footswitch. Unintentional activation may occur if the footswitch is activated by a separate user, which may result in patient or user injury.
- Ensure that the sound volume on the Generator is adequately adjusted so that the activation tones are clearly heard. The activation tones are intended to alert the user that the device is active. This will help prevent unintended contact with the device which could result in patient or user injury.
- Examine the handpiece before connecting it to the AEX™ Generator. After connecting the handpiece, ensure that the handpiece and the unit are functioning as intended.
- Consult the operating and user manuals for light sources and other ancillary devices for warnings, precautions, and instructions prior to their use with the AEX™ Generator.
- Position the AEX™ Generator away from life supporting and/or monitoring systems to reduce/avoid interference with these systems.
- The interference produced by the operation of RF surgical equipment may adversely influence the operation of other electronic equipment.
- DO NOT use electrosurgery in the presence of flammable anesthetics or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents as fire could result.
- The cable on the disposable handpieces should be positioned in a way to avoid contact with the patient or other cables.
- Monitoring systems incorporating RF current limiting devices are recommended.
- For surgical procedures where the RF current could flow through parts of the body having a relatively small cross sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
- During use, a diminished power output may indicate that the Patient Return Electrode connection has been compromised, failure of an electrical lead, active electrode insulation failure or excessive eschar buildup on the active electrode tip. Do not increase the power output before checking for obvious defects or improper connections. Check for effective contact of the Patient Return Electrode to the patient any time that the patient is moved after initial application of the Patient Return Electrode.
- If the system resets due to a power interruption or low voltage, the system will check for effective contact of the Patient Return Electrode, however the user should verify effective contact of the Patient Return Electrode visually prior to resuming electrosurgery.
- If power levels were increased to compensate diminished performance, it is recommended to reduce power to the original or a lower level upon resumption of use.
- The output power selected should be as low as possible for the intended purpose.
- Failure of the high-frequency surgical equipment could result in an unintended increase of output power.

- Do not use Monopolar electrosurgery on small appendages, such as in finger surgery, as it can cause thrombosis or other unintended injury to tissue proximal to the surgical site.
- Studies have shown that smoke generated during electrosurgery may be harmful to surgical personnel. These studies recommend the use of a surgical mask and adequate ventilation of the smoke using a surgical smoke evacuator or other means.
- Neuromuscular stimulation can occur causing unexpected patient movement, especially with modes producing electrical arcs between the active device electrode and tissue. Use caution in proximity to neural structures.
- Observe all caution and warning notices printed on the unit.
- Operating room staff should never contact the handpiece tip while the Generator is active, as injury may result.
- The tip of a recently activated handpiece may be hot enough to cause patient burns or ignite surgical drapes or other flammable material. When not in use, store the device in an electrically insulated container or holster. Never place or rest a handpiece on the patient.

▲ Warnings for Testing or Servicing

- Do not remove the Generator cover due to electrical shock hazard. There are no user serviceable parts inside.
- Never remove or install any parts with power ON, as this may result in potential for electrical shock or injury. Use only Medtronic Advanced Energy approved replacement parts in order to avoid potential equipment damage or injury.
- Avoid contact with the output leads when the Generator is activated as this may result in injury. Periodically inspect the test leads used for the output connections for obvious defects.
- The Generator is not designed to operate for extended periods of continuous output. When testing, it is recommended that duty cycles be limited to 25% with maximum activation times of 10 seconds into a load greater than or equal to 600 ohms. Use for an extended period of time may result in overheating and equipment damage.
- Periodic maintenance should be performed by a hospital qualified biomedical technician or by a qualified Medtronic representative.
- Minimizing operating temperature and extreme thermal cycles will extend the equipment life.
- The heat dissipation capability of the Generator heat sink may be severely impaired by activating the AEX™ Generator in other than a normal operating position. Testing or using the unit in any other position should be avoided.

2. Introduction

AEX™ Generator

The AEX™ Generator is one component of the AEX™ Surgery System. The Generator provides radio frequency (RF) energy to disposable Monopolar and Bipolar electrosurgical handpieces. The AEX™ Generator accepts a Patient Return Electrode for monopolar applications, and includes a rotary peristaltic pump for simultaneous delivery of saline for a hemostatic sealing.

Figure 2-1. AEX™ Generator and AEX™ Wireless Footswitch

AEX™ Generator

AEX™ Wireless Footswitch

RF Power

The AEX™ Generator delivers Bipolar RF power and saline with power settings in 5 watt increments in the range of 20 to 100 Watts and 10 Watt increments in the range of 100 to 220 Watts. The AEX™ Generator delivers Monopolar Cut, Coag, and Transcollation RF energy with a power output capable of up to 90 Watts. All PlasmaBlade™ handpieces powered by the PlasmaBlade™ port contain an embedded chip dictating the settings for that particular handpiece. Aquamantys™ handpieces do not have embedded chips. These settings are described in the Instructions For Use accompanying the handpiece.

Simultaneous RF Power and Saline Delivery

The AEX™ Generator simultaneously delivers RF power and saline to Bipolar Handpieces and certain Monopolar Handpieces when they are properly connected to the unit and the activation button on the handpiece is depressed. For a list of all compatible simultaneous handpieces, please contact Medtronic Advanced Energy Customer Service at +1 866 777 9400.

Saline Flow Rate Setting

The saline flow rate setting is determined based on the power setting and the selection of one of three possible flow rate settings: Low, Medium, and High. The three possible saline flow rates for each power setting are preset automatically in order to provide the optimal saline flow for a given power setting.

Priming

The AEX™ Generator has a convenient one touch priming function which automatically primes the Transcollation handpiece with saline prior to use after the device has been correctly connected to the unit. This function is activated by pressing the "PRIME" button on the unit.

Electrosurgical Modes

The AEX™ Generator operates in the following modes:

Cut Modes (Monopolar)

- Low Cut (Peak Cut) – Precision cutting with minimal hemostasis and minimal collateral damage
- Medium Cut (Pure Cut) – Precision cutting with increased hemostasis and collateral damage
- High Cut (Blend Mode) – Precision cutting with strong hemostasis

Coagulation Modes (Monopolar)

- Coagulation increases with higher settings.
- Low Coag (Pinpoint)
- High Coag (Spray)

Hemostatic Sealing Modes (Monopolar or Bipolar)

- Simultaneous delivery of RF energy with saline for hemostatic sealing of soft tissue and bone.

■ **IMPORTANT:**

- Each cut, coagulation, and seal mode has multiple power settings available.
- Handpiece models vary and may not utilize all modes. Available modes for each handpiece are per applicable handpiece Instructions For Use.

Other features of the AEX™ Generator include:

- Proprietary handpieces developed by Medtronic Advanced Energy to deliver RF energy to the patient. Only Medtronic Advanced Energy handpieces may be used with the AEX™ Generator.
- Handpiece control
- Handpiece with footswitch control
- Simultaneous activation of 2 handpieces
- Device default settings recognition
- Monopolar and Bipolar outputs
- Connection to Patient Return Electrode
- Color LCD to prompt user for input and to display informational, error, and fault messages
- Audio feedback of activation and alarm tones

Controls, Displays, and Receptacles

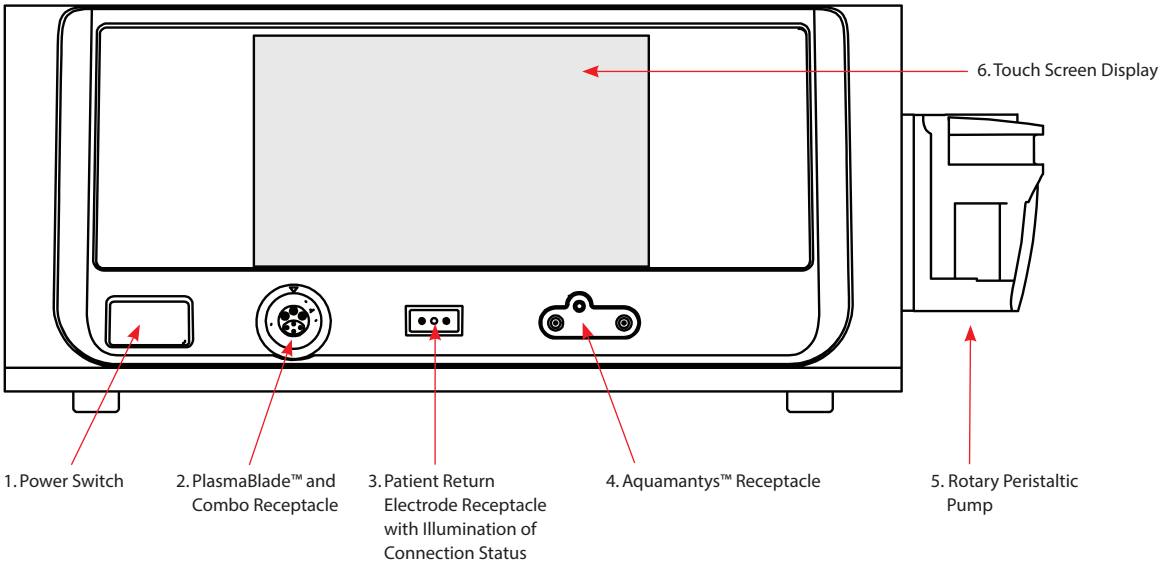
This section describes each component of the AEX™ Generator and its function. The controls, displays, and receptacles for Monopolar and Bipolar handpieces, Patient Return Electrodes, and the footswitch are located on the front and rear panels of the Generator.

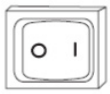
▲ **WARNING:** Read all warnings and instructions provided with the Generator prior to use.

Front Panel Layout Description

Refer to Figure 2-2 for a complete front panel illustration. Each display, control, or receptacle is described in more detail below.

Figure 2-2. Front Panel Layout



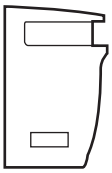


1. Power Switch – A black rocker switch that toggles right to turn the AEX™ Generator power on and toggles left to turn the power off.

2. PlasmaBlade™ and Combo Receptacle – A seven-pin circular receptacle that accepts PlasmaBlade™ and Combo handpieces.

3. Patient Return Electrode Receptacle – A standard two-pin receptacle that accepts the Patient Return Electrode connector used in Monopolar procedures.

4. Aquamantys™ Receptacle – A three-pin rectangular receptacle that accepts Aquamantys™ handpieces.



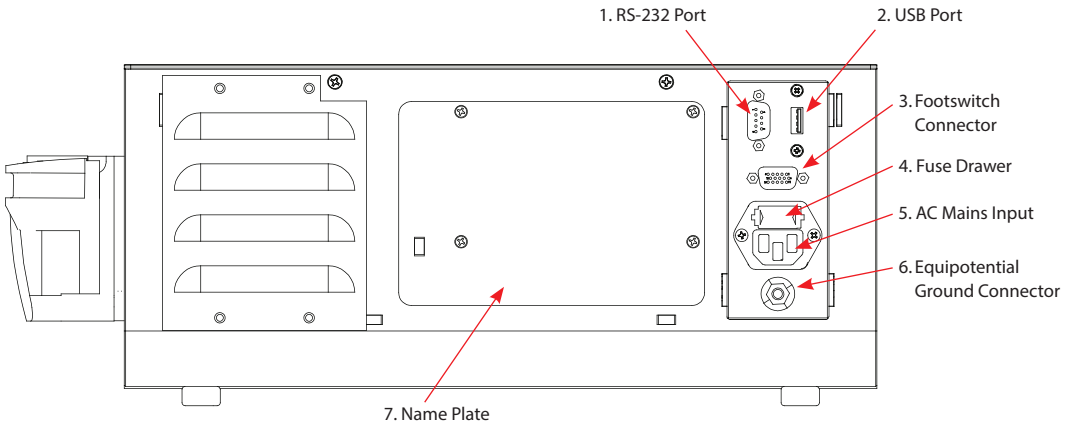
5. Saline Pump – This is a rotary peristaltic pump. A special pump segment is attached to the saline delivery tubing of each disposable handpiece which is designed to operate with the pump. The pump segment is loaded into this pump head prior to operation of the device.

6. Touch Screen Display – Screen used to prompt the user for input and to display informational and fault messages to user.

Panel Layout Description

Refer to Figure 2-3 for a complete back panel illustration. Each control, receptacle, or panel is described in more detail below.

Figure 2-3. Back Panel Layout



1. RS-232 Port – Service port for use by trained personnel only.

2. USB Port – Enables uploading of software and downloading of usage data.

3. Footswitch Connector – A connector that accepts an AEX™ Wireless Footswitch connector.

4. Fuse Drawer – This fuse drawer contains two fuses.

5. Power Entry / AC Mains – The power entry module combines the connector for the 3-prong, Hospital-Grade power cord with removable enclosure holding two line fuses. Always use fuses of the rating shown in "Mains Input Characteristics" on page 7-2 of this manual.

- **NOTE:** "Use Hospital Grade receptacle for grounding reliability" statement applies to US/North America power cords only.

6. Equipotential Ground Connector – Standard connector for connecting common grounds.

7. Name Plate – This plate specifies the model number, serial number, nominal line voltages, frequency, current, and fuse rating information for the AEX™ Generator.

This page intentionally left blank.

3. Installation

Initial Inspection

Unpack the Generator upon receipt and physically inspect it for any obvious damage that may have occurred during shipment. A qualified biomedical engineer or personnel familiar with electrosurgical devices should perform this inspection.

If the Generator is damaged, call +1 866 777 9400 for assistance.

Installation

The AEX™ Generator should be placed on a flat and stable surface.

▲ **WARNING:** The Hospital Grade power cord of the Generator should be connected to a properly polarized and grounded power source whose voltage and frequency characteristics are compatible with those listed on the nameplate of the AEX™ Generator (located on the rear panel of the Generator). Improper grounding may result in equipment damage, fire at the receptacle, or injury to the patient or user.

To completely disconnect the Generator from the AC mains, the power cord needs to be unplugged from the power source. Do not position generator such that removal of the power cord from the power source would be difficult.

● **NOTE:** "Use Hospital Grade receptacle for grounding reliability" statement applies to US/North America power cords only.

▲ **WARNING:** To allow for appropriate cooling, do not install the Generator in a cabinet or similar enclosure. If mounted on a shelf or near a wall, allow a 3-inch clearance around the Generator to permit free air circulation on all sides. Appropriate cooling is necessary to avoid overheating of the Generator.

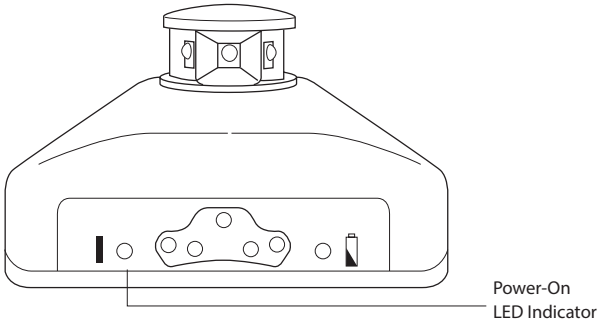
Optional Wireless Footswitch

- **NOTE:** The optional wireless footswitch is only compatible with enabled monopolar handpieces. Monopolar activation may be initiated either from a footswitch or a handpiece. Transcollation function cannot be activated by the footswitch.

1. If using the optional footswitch, plug the wireless receiver into the footswitch connector of the AEX™ Generator (see Figure 2-3 on page 2-4).

2. Turn on the AEX™ Generator and ensure that the wireless receiver's power-on LED is green, indicating that the receiver is powered on.

Figure 3-1. Wireless Receiver



▲ **WARNING:** Only the primary surgeon using the handpiece should operate the footswitch. Unintentional activation may occur if the footswitch is activated by a separate user, which may result in patient or user injury.

Refer to the *Wireless Footswitch Operator's Manual* for detailed product information.

Preliminary Checks

Prior to installing and using the Generator, it is strongly recommended that a qualified maintenance technician ensure proper and safe operation by testing the performance of the Generator. If anomalous behavior is observed, the Generator should not be used until all issues have been resolved by a qualified technician. Call Medtronic Advanced Energy Customer Service at +1 866 777 9400.

Preliminary Functional Testing

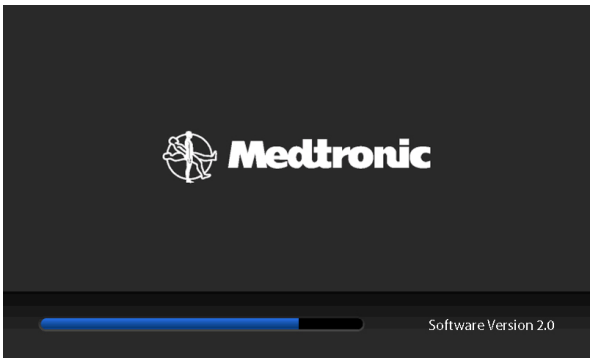
Preliminary functional testing should be conducted by a qualified technician or operating room personnel. Personnel conducting functional tests should read this manual prior to testing.

1. Turn on the Generator by pressing the power switch.

2. Verify the following occurs:

   - A self-test screen appears indicating that the system is performing a power-on self-test as shown in Figure 3-2. The software version is also shown at the bottom of the screen. If the self-test screen does not appear, cycle the power and try again. If the same problem continues, call Medtronic Advanced Energy Customer Service at +1 866 777 9400. Do not attempt to use the Generator until the problem has been resolved.

Figure 3-2. Front Panel Showing Self-Test Screen.



- The Cut and Coag activation tones will sound to allow you to verify operation.
- The screen in Figure 3-2 will disappear when the self-test is complete. If the self-test is not successful, an alarm tone will sound, a Fault Code will be displayed on the LCD screen and the Generator output will be disabled. The alarm tone will sound until the Generator is turned off. In this case, call Medtronic Advanced Energy Customer Service. Do not attempt to use the Generator until the problem has been resolved.
- If the self-test is successful, verify the following:
- If the Generator is powered on with *no handpieces connected,* the Generator displays the following operational screen.

Figure 3-3. Front Panel Showing Operational Screen with No Devices Connected.

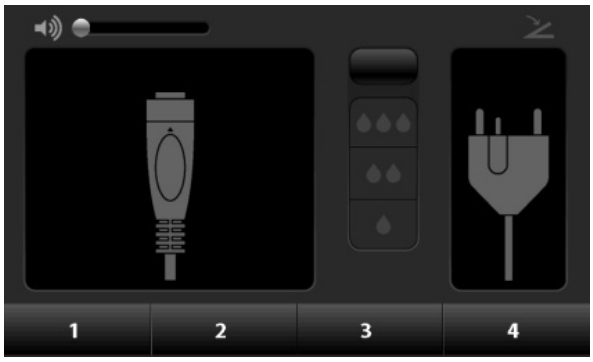


Figure 3-4. Front Panel Displaying the Screen with PlasmaBlade™ Handpiece Connected.

Figure 3-5. Front Panel Displaying the Screen with Bipolar Handpiece Connected.

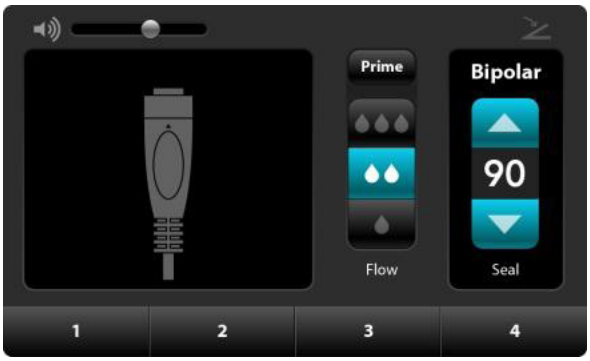


Figure 3-6. Front Panel Displaying the Screen with PlasmaBlade™ and Bipolar Handpieces Connected.

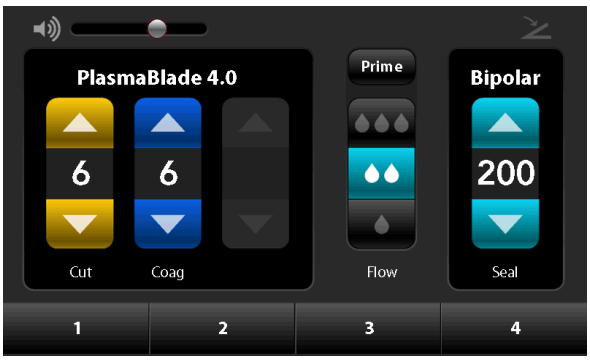


Figure 3-7. Front Panel Displaying the Screen with Combo Handpiece Connected.

Figure 3-8. Front Panel Displaying the Screen with PlasmaBlade™ and Bipolar Handpieces Connected and activated.

4. Operation

Using the Touch Screen

The following are some typical examples of the touch screens and how to interact with them:

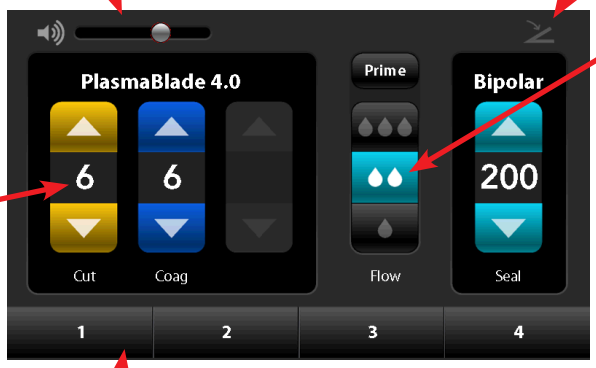
Figure 4-1. Touch screen

Sound Volume Control

Slide the control to the right to increase the volume, slide the control to the left to decrease the volume.

Footpedal Indicator

It is illuminated if a footswitch is connected.



Saline Flow Rate Indicators

Press one of the three indicators.

Power Levels

Increase by pressing up arrow, decrease by pressing down arrow.

Memory Buttons

They can be renamed by pressing and holding the button for 1 second. Then a keyboard will appear. Alpha and numeric keyboards are available (see Figures 4-2 & 4-3). In order to preset the memory button with power level preferences, the handpieces need to be plugged in to the AEX™ Generator display. Then change the handpiece power levels. Once the power levels have been changed, press and hold the memory button to save the preferences.

Figure 4-2. Numeric keyboard

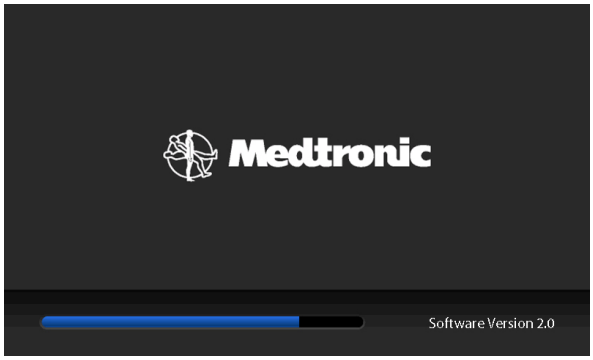
Figure 4-3. Alpha keyboard

Turn on Generator

1. Ensure the power switch is off, and then connect the power cord to a properly grounded and polarized mating power receptacle.

2. Set the power switch to the ON position. The color LCD on the front panel will illuminate and show a self-test screen (Figure 4-4). The self-test will take approximately 10 seconds to complete.

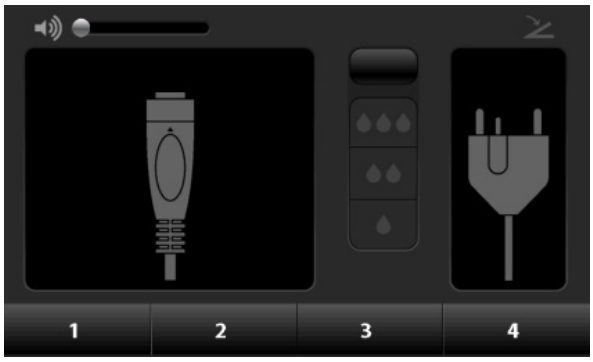
Figure 4-4. Self test.



After the Generator goes through its internal self-diagnostics, the Generator should respond by:

- The self-test screen will be replaced with an operational screen (Figure 4-5), and the generator will output a three tone sequence indicating the completion of self-test.

Figure 4-5. Operational screen.



After the power-on self-tests, the Generator is ready for use.

If the Generator fails to respond as indicated above, it has failed one of its internal tests and must not be used. An alarm tone will sound and a Fault Code will appear on the front panel LCD. As a result, the Generator output will be disabled. In this case, call Medtronic Advanced Energy Customer Service at +1 866 777 9400. Do not attempt to use the Generator until the problem has been resolved.

Connect the Patient Return Electrode to Patient and Generator

- **NOTE:** A Patient Return Electrode is only required for RF energy delivery if the Patient Return Electrode receptacle LED is illuminated while a handpiece is connected.

1. Select and prepare patient application site. Refer to the Instructions for Use provided with the Patient Return Electrode. To reduce risk of patient burns, apply Patient Return Electrode to patient observing the criteria described in Section 1 of this Operator's Manual and the Instructions for Use provided with the Patient Return Electrode.
2. Insert the Patient Return Electrode connector into the Patient Return Electrode receptacle in the center of the front panel of the AEX™ Generator (Figure 4-6).
3. When the Patient Return Electrode has been properly selected and applied to the patient, and a monopolar device has been connected, the Patient Return Electrode receptacle illumination will change from red to green in color (Figure 4-7).

Figure 4-6.

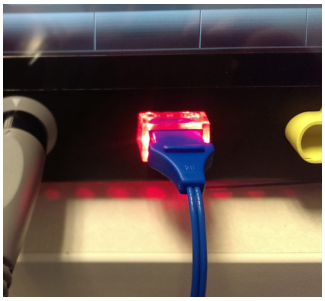
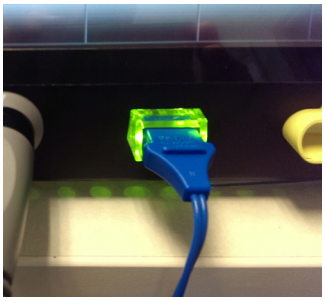


Figure 4-7.



▲ **WARNING:** Refer to the manufacturer's instructions for application site and placement procedures when applying the Patient Return Electrode.

▲ **WARNING:** Do not depend solely on the illumination indicator for confirmation of good Patient Return Electrode application. Qualified personnel should make the final decision on proper Patient Return Electrode placement.

■ **IMPORTANT:** Monopolar devices require a Patient Return Electrode. The Generator must detect proper Patient Return Electrode impedance before the Generator output can be active.

■ **IMPORTANT:** The AEX™ Generator accepts both single foil and split foil Patient Return Electrodes up to power levels of 50 watts. If a hand piece with monopolar capability exceeding 50 Watts is connected to the generator, a split foil Patient Return Electrode is required.

Plugging in the Handpiece to the AEX™ Generator

PlasmaBlade™

1. Insert the handpiece connector into the gray PlasmaBlade™ receptacle on the front panel of the AEX™ Generator.

■ **IMPORTANT:** Upon connection, the Generator will alarm if the device is not recognize the handpiece, if it fails a unit test, or if it is expired.

2. The screen will display default output levels for Cut and Coag (Figure 4-8).

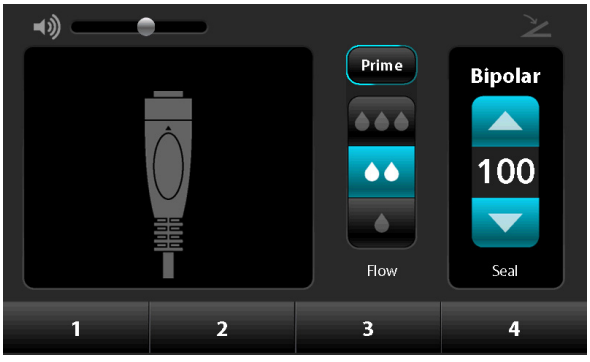
Figure 4-8. Default Cut and Coag output levels

▲ **WARNING:** Always stow unused devices in an electrically insulated location such as a safety holster in sterile field.

Aquamantys™ Handpiece

1. Insert the handpiece connector into the yellow Aquamantys™ receptacle on the front panel of the AEX™ Generator.
2. The touchscreen will display the default output level for Bipolar power and a glow around the "Prime" button to prompt saline setup (Figure 4-9).

Figure 4-9. Default Bipolar output level



▲ **WARNING:** Always stow unused devices in an electrically insulated location such as a safety holster in sterile field.

Combo Handpiece

1. Insert the handpiece connector into the gray PlasmaBlade™ 7-pin receptacle on the front panel of the AEX™ Generator.

■ **IMPORTANT:** Upon connection, the Generator will alarm if the device is not recognized as a Combo handpiece, if it fails a unit test, or if it is expired.

2. The screen will display default output levels and a glow around the "Prime" button to prompt saline setup (Figure 4-10).

Figure 4-10. Default output levels

● **NOTE:** If two handpieces with transcollation technology are connected to the generator, the generator will only permit use of transcollation on the 3-Pin receptacle powered handpiece. Only the 3-Pin handpiece saline tubing should be loaded in this instance.

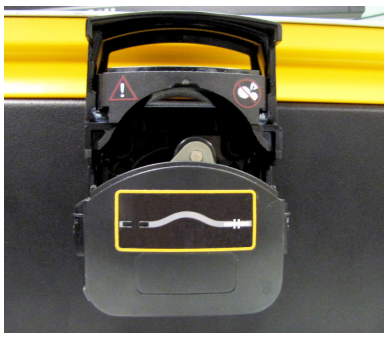
Handpiece use requires compatible generator software. If the generator software is not compatible with its connected handpiece, the handpiece will not function.

▲ **WARNING:** Always stow unused devices in an electrically insulated location such as a safety holster in sterile field.

Loading the Pump Segment Portion of the Handpiece into the Pump Head of the AEX™ Generator

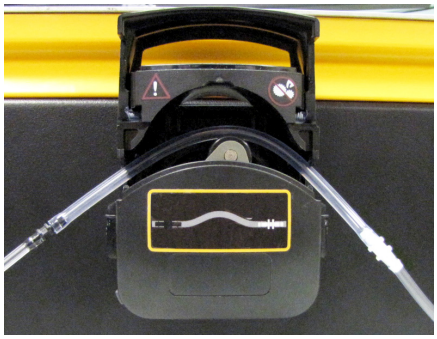
1. Raise the upper part of the pump head by flipping open the pump lid as shown in Figure 4-11.

Figure 4-11. Open pump lid



2. On the handpiece saline tubing, locate the pump segment portion (between black and white tubing connectors), place the pump segment portion of the saline delivery tubing into the pump head with the black tubing connector positioned to the left side of the pump head (i.e., closest to the front panel of the AEX™ Generator). The white tubing connector should then be positioned to the right side of the pump head (i.e., closest to the back panel of the AEX™ Generator). A label on the front of the pump indicates the position of the black and white connectors.

Figure 4-12 Open pump lid



■ **IMPORTANT:** Ensure that the pump segment portion of the saline delivery tubing is properly aligned in the center of guide slots (upside down "v") where it enters and exits the pump head.

3. Close the pump head.

   The pump segment tubing must be centered in the guide slot of both tubing guides, with no pinching of the tubing (see Figure 4-13).

Figure 4-13 Closed pump

▲ **WARNING:** Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the pump segment of the disposable bipolar device in the pump head while the pump head rotor is turning. Fingers or loose clothing could be caught in the pump rollers.

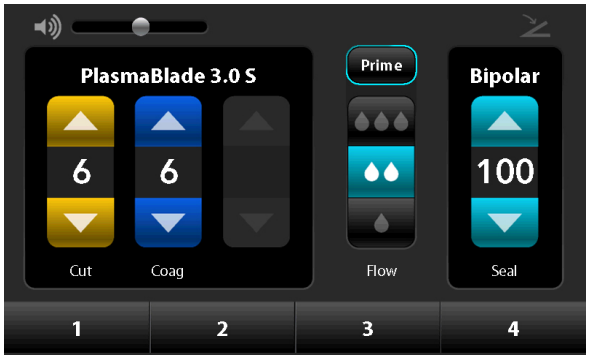
Spiking the Saline Bag

1. Hang a bag of sterile saline (0.9% NaCl) solution on the AEX™ Generator Cart I.V. pole or another I.V. support that is in close proximity to the AEX™ Generator.
2. Remove the protective cover over the spike of the drip chamber at the end of the handpiece's saline delivery tubing.
3. Using aseptic technique, spike the bag of sterile saline (0.9% NaCl) solution.
4. Squeeze the drip chamber once or twice to fill the drip chamber to a level of at least one-third full.

Priming the Handpiece

1. Press the "PRIME" button as shown in Figure 4-14. This initiates priming of the handpiece with saline.
   - The pump will operate for a preset time period to prime the device. The pump head speed is accelerated during the priming cycle compared to normal use.
   - The device is primed when saline drips from both device electrodes of the handpiece. After the priming cycle is complete, the pump shuts off automatically.

Figure 4-14. Prime Button Screen



2. The "PRIME" indicator will change to "STOP" when priming is activated. If priming needs to be stopped after priming has been initiated, press the "STOP" button as shown in Figure 4-15.

Figure 4-15. Stop Button Screen

3. After the initial priming of the handpiece, the button is renamed "REPRIME" as shown in Figure 4-16.

Figure 4-16. Reprime Button Screen

▲ **WARNING:** Always place the handpiece into a holster or over a container to collect the saline that exits the device electrodes as a result of the priming process. If excess saline is not collected, saline could drip on the patient, patient drapes, surgical instruments, or operating room surfaces.

▲ **WARNING:** Lack of saline flow from both of the device electrodes can result in a lack of tissue effect and may damage the device electrodes during device activation. Use caution to avoid conditions that can result in lack of adequate saline flow from the device.

Adjusting RF Power Levels

▲ **WARNING:** Set the RF power to the lowest setting for desired tissue effect to avoid overtreatment, which could result in swelling, fluid, seroma or unintended tissue necrosis. Setting the RF power too low may produce insufficient tissue effect.

1. Set the RF power output for the desired tissue effect by pressing the ▲ button to increase, or the ▼ button to decrease, RF power.
2. Release the button when the desired RF power setting is displayed. The final RF power settings will be shown on the screen.

■ **IMPORTANT:** The RF power setting cannot be adjusted while the handpiece is being activated.

3. The default power setting and the range of possible power adjustments will depend upon which disposable handpiece is inserted into the AEX™ Generator. The range of power settings for each handpiece have been selected to optimize its performance.

Adjusting the Saline Flow Rate

1. The saline flow rate may be adjusted by pressing the desired flow rate button. The three flow rate buttons are:
   - High Flow (💧💧💧)
   - Medium Flow (💧💧)
   - Low Flow (💧)
2. The three possible saline flow adjustments are preset for each given RF power setting.

● **NOTE:** The saline flow rate setting cannot be adjusted while the disposable hand piece is activated.

3. If a flow rate setting is not manually selected, the medium setting is selected as the default setting.

Activating the Handpiece

The AEX™ Generator is designed to control RF energy output within specifications when activated.

If the AEX™ Generator fails to activate, the RF Power Activation Indicator will not illuminate and no audible indicator will be heard. If the AEX™ Generator fails to meet RF Energy output specifications during use, RF energy output will stop. The generator will alarm and present an error code on the display, indicating to the operator that an error has occurred.

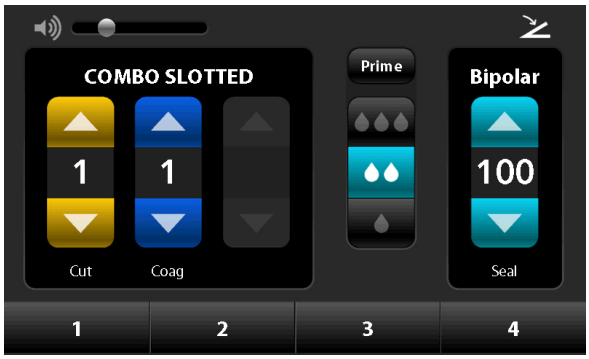
1. Press the activation button on the handpiece to simultaneously activate RF power and saline flow (if applicable) from the handpiece. The appropriate indicator on the touch screen will illuminate and the appropriate activation tone will sound.
2. Release the activation button on the handpiece to shut off both RF power and saline flow from the handpiece.

At maximum output settings and rated load conditions, the generator may be safely operated at duty cycles of 33% for bipolar Transcollation (40 seconds on, 80 seconds off), and 25% for monopolar RF delivery (10 seconds on, 30 seconds off).

Using an Optional Footswitch

An optional footswitch may be used. If a footswitch will be used, plug the wireless receiver into the footswitch connector on the back of the generator (see Figure 2-3 on page 2-4). While using a footswitch, RF power will be delivered via the handpiece.

Figure 4-17. Footswitch Connected



▲ **WARNING:** Ensure that the footswitch is not inadvertently depressed to prevent the device from being unintentionally activated. Place the footswitch in a location that requires deliberate action in order to activate the unit.

■ **IMPORTANT:** Use only the AEX™ Wireless Footswitch.

Adjusting RF Power Settings Using Memory Buttons

Once a Memory Button has been set up with appropriate settings, a user can select a memory button and the settings that have been preset will automatically become active for the hand pieces that are plugged into the AEX™ Generator.

Adjusting the Volume of the Activation Tone

▲ **WARNING:** Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when a device is active.

- To increase the volume of the RF power activation tone, slide the button to the right.
- To decrease the volume of the RF power activation tone, slide the button to the left.
- The AEX™ Generator prevents this tone from being silenced.

After Surgery

Disposing of the Handpiece

1. Turn the Generator off by pressing the left half of the power switch.
2. If the handpiece has saline tubing, firmly knot the saline tubing between the drip chamber and the pump segment.
   - Open the pump head and remove the pump segment portion of the saline delivery tubing.
   - Remove the used saline bag from I.V. pole.
3. Unplug the handpiece from the AEX™ Generator.
4. Dispose of the handpiece and used saline bag according to the procedures for your institution.

■ **IMPORTANT:** Some handpieces and the saline bags will contain unused saline following use of the handpiece. Take precautions to prevent the unused saline from flowing onto operating room surfaces by placing handpiece into waste receptacle prior to opening pump head and removing device pump segment.

Preparing the AEX™ Generator for Reuse

▲ **WARNING:** ***Electric Shock Hazard.*** Always turn off and unplug the unit before cleaning.

■ **IMPORTANT:** Do not clean the unit with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the unit.

1. Turn the AEX™ Generator off by pressing the left hand portion of the power switch.
2. Unplug the main power cord from the wall outlet and receptacle on the AEX™ Generator.
3. Thoroughly wipe all surfaces of the unit and power cord with a damp cloth using a mild cleaning solution or disinfectant. Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. The unit should not be sterilized.

Transportation and Storage of the AEX™ Generator

Care should be taken when transporting the AEX™ Generator prior to and after use to prevent impact damage to the unit. The unit should be transported on the AEX™ Generator Cart or a suitable alternative. Consult the procedures for your institution and applicable regulations.

If the unit is stored at a temperature outside its normal operating range of 50 °F to 104 °F (10 °C to 40 °C), allow it to stabilize at room temperature prior to use.

The unit can be stored indefinitely. However, if you store it longer than one year, you must perform specific checkout procedures, including functional verification before use.

Do not store the AEX™ Generator on its side or end. This may cause damage to the unit.

- **IMPORTANT:** Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner by a certified disposal company.

5. Cleaning and Maintenance

This section contains information for ordinary cleaning and maintenance of the AEX™ Generator. While the Generator has been designed and manufactured to high industry standards, periodic inspection and performance testing must be performed by a qualified biomedical technician for safe and effective operation.

● **NOTE:** Refer to the *AEX™ Service Guide* for more detailed information and instructions.

Inspections Required Before Each Use

1. Visually inspect the Generator for physical damage. Report damage to Medtronic Advanced Energy or your biomedical department. Do not use the Generator if it is damaged.
2. Visually inspect the power cord and plug for physical damage. Replace the cord if the insulation has been breached. Do not use the Generator if the cord or plug has been damaged and has not yet been replaced.

Required Annual Inspections

1. Inspect the tightness of the power plug. If this component is loose, it must be replaced with a Medtronic Advanced Energy approved component.
2. Inspect the mating, cleanliness, and absence of damage to the patient connectors. Do not use the Generator if the connectors are damaged.
3. Inspect for accumulation of lint or debris on the Generator or fan vents. Do not use the Generator if lint or debris has accumulated and has not been cleared.

Cleaning

▲ **WARNING:** ***Electric shock hazard.*** Always unplug the Generator from the wall outlet prior to cleaning.

The Generator does not require sterilization.

1. Clean the front display, cover, and cord with a mild detergent or mild disinfecting solution and damp cloth.

It is recommended that non-flammable agents be used for cleaning and disinfection whenever possible. If flammable agents are used for cleaning, disinfecting, or as solvents, they should be allowed to dry before surgery.

◆ **CAUTION:** Do not allow fluids to enter the chassis. Do not use alcohol, caustic, corrosive, or abrasive materials on the front display, cover, and cord, as they may cause damage to the equipment. Medtronic Advanced Energy recommends following hospital procedures for cleaning the outside of the Generator after each procedure.

Refer to the *AEX™ Wireless Footswitch Operator's Manual* for detailed cleaning instructions for the footswitch and receiver.

Maintenance

The AEX™ Generator must be performance tested by a hospital qualified biomedical technician at least every year. Follow your hospital's procedures for periodic performance verification of electrosurgical generators. Medtronic Advanced Energy recommends performing a Power Output verification check for each mode of operation.

Service

The RS-232 port provided on the rear panel is used for the following service features, which can be performed by a qualified Medtronic Advanced Energy technician only:

- To reprogram set-up parameters.
- To download the event history log containing information on errors and faults.

Storage

The Generator must be thoroughly checked by a qualified biomedical engineer if it has been stored for longer than 6 months.

Allow the Generator to remain at room temperature for at least 1 hour if it has been stored at extreme temperatures. Refer to "Storage Parameters" on page 7-1 for the limits for storing the AEX™ Generator.

Environmental Protection

Retain the shipping container and packing material in the event that the Generator needs to be returned for repair or service. At the end of the equipment's life, dispose of it in accordance with your local regulations. The materials in the generator include aluminum, steel, copper, thermoplastics, and electronic components.

6. Troubleshooting

This section identifies the possible error and fault conditions and offers common solutions for correcting malfunctions and responding to alarms.

The AEX™ Generator has been designed and manufactured for reliable operation. In the event that the Generator fails, it has several self-diagnostic routines to aid in troubleshooting the problem. If the software detects a problem, an error code or fault code is displayed on the screen, and the Generator is disabled. The Generator will remain disabled until the detected problem is corrected. The self-diagnostic routines are only an aid for qualified technicians, and are not a substitute for evaluation of a problem by a qualified technician.

▲ **WARNING:** ***Electric shock hazard.*** Always unplug the Generator from the wall outlet prior to opening the cover for servicing. There are no user-serviceable parts inside the Generator. The AEX™ Generator should only be serviced by a Medtronic Advanced Energy trained technician.

Monopolar and Bipolar Errors

The AEX™ Generator includes automatic self-diagnostics. If the diagnostics detect a condition that can be corrected by the operator, the system displays an error code, sounds an alarm tone, and deactivates the Generator's output. Correcting the error will enable the Generator's output.

Most error codes result from conditions in accessories attached to the Generator. The following table lists the error codes and describes the condition.

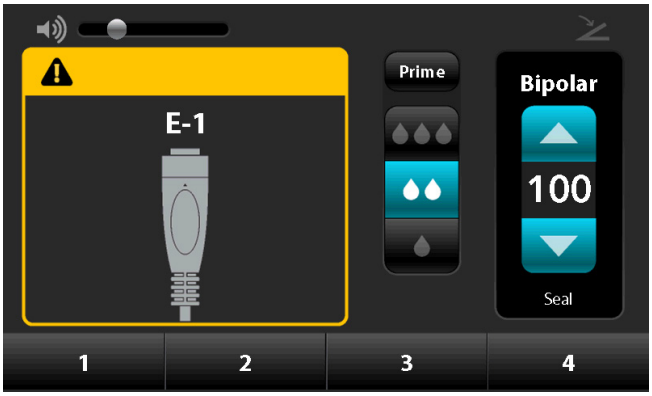
Table 6-1. Error Codes

Error Code	Description
E1	Switch on handpiece may be stuck in the ON position.
E2	Footpedal switch may be stuck in the ON position.
E3	Patient Return Electrode has poor connection.
E4	Generator monopolar output error.
E5	Handpiece has reached end of life.
E6	Handpiece is not recognized as a Medtronic Advanced Energy device or failed test.
E7	Generator bipolar output.
E8	Monopolar output circuitry has exceeded a normal temperature.
E9	Patient Return Electrode is not supported by current handpiece.
E10	Handpiece must be Primed before performing Transcollation.

Error Code Details

A detailed description of the cause of each error is provided below, along with steps to follow. Figure 6-1 shows an example of an Error screen.

Figure 6-1. Error Code E1



Error Code E1

Switch on handpiece may be stuck in the ON position.

Cause	Solution
Handpiece button stuck in the ON position when the device is connected. The Error Code is displayed and the alarm will sound once.	1. Ensure that the handpiece is not in contact with the patient. 2. Disconnect and reconnect the handpiece. 3. If the Error Code reappears, turn the Generator power OFF and then turn the power ON again. 4. If the problem persists, replace the handpiece and repeat this procedure. 5. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Code E2

Foot pedal switch may be stuck in the ON position.

Cause	Solution
Footswitch has pedal switch stuck in the ON position when the footswitch is connected. The Error Code is displayed and the alarm will sound once.	1. Ensure that the handpiece is not in contact with the patient. 2. Disconnect and reconnect the footswitch. 3. If the Error Code reappears, turn the Generator power OFF and then turn the power ON again. 4. If the problem persists, replace the footswitch and repeat this procedure. 5. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Code E3 with Red LED Illumination

Patient Return Electrode has poor connection or no connection.

Cause	Solution
The Error Code is displayed when the impedance is out of range. The Error Code is displayed and the alarm will sound once. The error/alarm will only display/ sound if the handpiece is activated. The Patient Return Electrode receptacle LED Illumination will turn red and stay red as long as the impedance is out of range. The Patient Return Electrode impedance is continuously checked.	1. Follow the manufacturer's instructions for Patient Return Electrode placement. 2. Verify that a Split Foil Patient Return Electrode is used for handpieces with power levels greater than 50 watts. 3. Verify that the Patient Return Electrode is connected to the Generator. 4. Verify the Patient Return Electrode is making proper contact with the patient. 5. Disconnect and reconnect the Patient Return Electrode and Generator. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Code E4

Generator monopolar output error.

Cause	Solution
Measurements of the monopolar output voltage and current are being made while the Generator has active output. If these measurements are outside the normal range, the output will be disabled. The Error Code is displayed and the alarm will sound once.	1. If the Error Code reappears, replace the handpiece. 2. If the Error Code reappears, disconnect the handpiece and the Patient Return Electrode. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and try again. 3. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Code E5

Handpiece has reached end of life.

Cause	Solution
For safety reasons, each device has a limited active life span. If the time is exceeded, then the Error Code is displayed and the alarm will sound once.	1. Replace the handpiece. 2. The Error Code screen will disappear if the device is recognized, tested, and has a life expectancy. 3. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Code E6

Handpiece is not recognized as compatible.

Cause	Solution
The handpiece is connected to the Generator and it is not recognized as an AEX™ device, a generator software update is needed, or it has failed testing. The Error Code is displayed and the alarm will sound once.	1. Replace the handpiece. The Error Code screen will disappear if the device is recognized, tested, and has a life expectancy. 2. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Code E7

Generator bipolar output error.

Cause	Solution
Measurements of the bipolar output voltage and current are being made while the Generator has active output. If these measurements are outside the normal range, the output will be disabled. The Error Code is displayed and the alarm will sound once.	1. If the Error Code reappears, replace the handpiece. 2. If the Error Code reappears, disconnect the handpiece and the Patient Return Electrode. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and try again. 3. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Code E8

Monopolar output circuitry has exceeded a normal temperature.

Cause	Solution
Intensive use of high power output can cause significant increase in the generator circuit temperature. If the temperature is determined to exceed a normal level, the monopolar transcollation output will be disabled. The error code is displayed and the alarm will sound once.	1. Release the transcollation button on the handpiece. 2. Cut and Coag use may be continued. 3. The error code will remain on the screen until the generator circuit temperature has returned to a normal level. While the error code is displayed, monopolar transcollation will be deactivated.

Error Code E9

Patient Return Electrode is not supported by current handpiece.

Cause	Solution
The connected handpiece has the capability of delivering greater than 50 Watts of monopolar RF power. A device with this capacity can only be used with a split foil Patient Return Electrode. The output will be disabled if the unlocked NE Impedance measures less than 18 Ohms while such a handpiece is connected. The Error Code will be displayed and the alarm will sound once.	1. Substitute a Split foil Patient Return Electrode for the Patient Return Electrode currently connected to the receptacle on the front of the generator. 2. If the Error Code reappears, disconnect the handpiece and the Patient Return Electrode. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and try again. 3. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Code E10

Handpiece needs to be primed before performing Transcollation.

Cause	Solution
The generator requires that all connected handpieces are primed before they can perform Transcollation. The Error Code is displayed and the alarm will sound once upon un-primed Transcollation activation attempt.	1. Press the Prime button on the display. 2. Allow the priming sequence to complete or press the Stop button to end priming. 3. Attempt Transcollation activation again. 4. If the Error Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Monopolar and Bipolar Faults

The AEX™ Generator includes automatic self-diagnostics. If the diagnostics detect a fault, the system displays a fault code, sounds an audible tone, and deactivates the Generator's output. All faults indicate a possible problem with the equipment. Power must be turned off and then back on before operation can continue. If the self-test does not successfully complete, refer the equipment to Service Personnel.

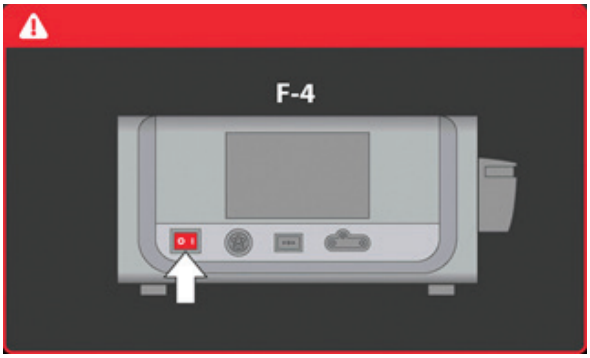
Table 6-2. Fault Codes

Non-Recoverable Fault Code	Description
F1	Internal temperature of the Generator has exceeded the limit.
F2	CRC self-test fault.
F3	RF Module not calibrated or calibration was lost.
F4	Real Time Clock self-test fault.
F5	Watchdog Monitor has detected a Watchdog Processor failure.
F6	Controller Processor communication with the Display has failed.
F7	Pump Communications fault.
F8	Pump Control Overheating.
F9	ADC Reference fault.
F10	RAM self-test fault.

Fault Code Details

A detailed description of the cause of each fault code is provided below, along with steps to follow. Figure 6-2 shows an example of a Fault screen.

Figure 6-2. Fault Code



Fault Code F1

Internal temperature of the Generator has exceeded the limit.

Cause	Solution
Internal temperature exceeded limit while turned ON. The Fault Code is displayed and the alarm will sound once.	1. Turn off Generator and turn back on after the Generator has cooled sufficiently. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F2

CRC self-test fault.

Cause	Solution
Self-test diagnostics are run when the Generator is powered ON. This Fault Code indicates that one or more of the self-tests have failed. The Fault Code is displayed and the alarm will sound continuously.	1. Turn the Generator power OFF and then turn the power ON again. Do not press buttons or activate handpieces during the self-test. 2. If the Fault Code reappears, disconnect the handpiece and Patient Return Electrode. Turn the Generator power OFF and then turn the power ON again. 3. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F3

RF Module not calibrated or calibration was lost.

Cause	Solution
The RF Module has detected that it is not calibrated or calibration values have been lost. The Fault Code is displayed until the Generator is turned off and the alarm will sound once.	1. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and re-attempt use of the handpiece. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F4

Real Time Clock self-test fault.

Cause	Solution
Self-test diagnostics are run when the Generator is powered ON. This Fault Code indicates that one or more of the self-tests have failed. The individual self-test that failed will be recorded in the Generator's data flash for retrieval during maintenance. The Fault Code is displayed until the Generator is turned off and the alarm will sound once.	1. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and re-attempt use of the handpiece. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F5

Watchdog Monitor has detected a Watchdog Processor failure.

Cause	Solution
The Watchdog Monitor has detected that the Processor Watchdog has engaged. The Fault Code is displayed until the Generator is turned off and the alarm will sound once.	1. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and re-attempt use of the handpiece. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F6

Controller Processor communication with the Display has failed.

Cause	Solution
The Controller processor has detected that the display communication is not functioning properly. The Fault Code is displayed until the Generator is turned off and the alarm will sound once.	1. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and re-attempt use of the handpiece. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F7

Pump Communications fault.

Cause	Solution
The Pump motor controller communications have failed. The Fault Code is displayed and the alarm will sound once.	1. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and re-attempt use of the handpiece. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F8

Pump Overheating.

Cause	Solution
The temperature of the pump's motor controller exceeded limit while turned ON. The Fault Code is displayed and the alarm will sound once.	1. Turn off Generator and turn back on after the Generator has cooled sufficiently. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F9

ADC Reference fault.

Cause	Solution
This Fault Code indicates that the Generator's analog to digital conversion circuitry has experienced a fault while turned ON. The Fault Code is displayed and the alarm will sound once.	1. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and re-attempt use of the handpiece. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Fault Code F10

RAM self-test fault.

Cause	Solution
Self-test diagnostics are run when the Generator is powered ON. This Fault Code indicates that one or more of the self-tests have failed. The Fault Code is displayed until the Generator is turned off and the alarm will sound once.	1. Turn the Generator power OFF and then turn the power ON again. Reconnect the handpiece and Patient Return Electrode and re-attempt use of the handpiece. 2. If the Fault Code reappears, record the number and contact Medtronic Advanced Energy Customer Service. Do not use the Generator.

Error Codes and Error Handling

The AEX™ Generator self-test, which is executed immediately following power up, comprises several phases. The first phase covers the internal RAM and the MPU0 watchdog test. The second phase tests the major computer hardware components (microcontroller). The third phase tests the NV-RAM and the separate RFGEN modules for potential errors. Portions of this self-test are repeated in the background during normal use.

If an error is detected, the respective test is repeated at least once in order to exclude sporadic deviations. If the deviation remains, the self-test aborts, an error message is generated, and the unit enters the safe state. The safe state disables functions of the pump generator until the error condition is cleared.

Troubleshooting Malfunctions

If a solution is not readily apparent, use the table below to help identify and correct specific malfunctions. After you troubleshoot the malfunction, verify that the unit completes the self-test as described in Section 4, *Operation*.

Table 6-3. Troubleshooting

Situation	Possible Cause	Solution
No power	No power cord.	Use power cord shipped with AEX™ Generator or contact Medtronic Advanced Energy Customer Service to obtain new power cord.
	Wrong power cord utilized.	Use power cord shipped with AEX™ Generator or contact Medtronic Advanced Energy Customer Service to obtain new power cord.
	Faulty wall outlet.	Insert power cord into a functioning wall outlet.
	Fuse drawer is open or fuses are blown.	Close the fuse drawer. Replace the blown fuse(s).
	Wrong fuse.	Use fuse listed in Section 7, *Specifications*. Correct fuse is also listed on back panel of the unit.
	Unit not turned on.	Switch unit on using the power switch located on the front panel of the unit.
	Insufficient insertion of device plug into receptacle.	Ensure disposable handpiece is fully inserted into receptacle.
	Insufficient insertion of power cord into unit or wall jack.	Ensure power cord is fully inserted into back of unit and wall jack.
	Damaged AEX™ Generator power cord.	Contact Medtronic Advanced Energy Customer Service to obtain a new power cord.
	Damaged disposable handpiece power cord.	Do not use device. Return the device to Medtronic Advanced Energy and use new device.
No saline when device activated	Pump tubing segment not inserted correctly into pump head.	Remove pump tubing segment from pump head and reinsert correctly as indicated in User Guide.
	Saline bag positioned on side or upside down.	Ensure saline bag is positioned right side up.
	Pump head not closed.	Close the pump head prior to use.
	No saline source.	Ensure spike at end of device tubing set is correctly inserted into a 250 ml or larger I.V. bag of sodium chloride solution (0.9%NaCl).
	Priming cycle not completed.	Press "PRIME" button once and ensure priming cycle completes and saline drips from both device electrodes.
	Priming button on unit pressed before the saline bag was spiked.	Press "PRIME" button once and ensure priming cycle completes and saline drips from both device electrodes.
	Inadequate supply of saline.	Ensure drip chamber is at least one-third (1/3) full.
		Replace used bag of sodium chloride solution (0.9%NaCl) with a new bag.

Table 6-3. Troubleshooting (continued)

Situation	Possible Cause	Solution
No saline when device activated (continued)	Pump tubing segment inserted in reverse orientation.	Ensure black connector on the tubing segment is oriented to the left side of the pump head and the white connector to the right side of the pump head when pump tubing segment is inserted.
	Saline line kinked/compressed/occluded.	Ensure disposable handpiece pump segment is properly aligned in the pump head. Ensure saline line is not kinked, compressed, or occluded by operating room equipment, instruments, or personnel.
	Non-AEX™ handpieces connected to AEX™ Generator.	Ensure device connected to AEX™ Generator is an AEX™ handpiece. If incorrect handpiece is being utilized, discard and utilize correct disposable handpiece.
	All saline slots in either of the device electrodes of the handpiece clogged by tissue or coagulated blood.	Clean device electrodes with gauze. Ensure precautions are taken to avoid inadvertent device activation when cleaning device electrodes. If this does not correct the problem, discontinue use and return device to Medtronic Advanced Energy and use new device.
	Pump is jammed by pump segment connector which has inadvertently entered into pump head.	Ensure pump segment is aligned in the center of guide slots (upside down "v") where it enters and exits the pump head.
	Source of normal saline is a non-vented glass bottle.	Open vent cap on handpiece drip chamber.
Incorrect saline flow when device activated	Pump tubing segment not inserted correctly into pump head.	Remove pump tubing segment from pump head and reinsert correctly as indicated in User Guide.
	Saline bag height below pump head.	Ensure saline bag is positioned at a height above the pump head.
	Saline delivery tubing inserted into pump head instead of pump tubing segment.	Ensure black connector on the tubing segment is oriented to the left side of the pump head and the white connector to the right side of the pump head when pump tubing segment is inserted.
	Air bubbles in line due to incorrect priming technique.	Press "PRIME" button once to reprime the device in order to remove air bubbles.
	Saline line kinked or compressed.	Ensure pump segment is properly aligned in the pump head. Ensure saline line is not kinked, compressed, or occluded by OR equipment, instruments, or personnel.
	Incorrect (non-AEX™) disposable handpiece utilized.	Ensure device connected to AEX™ Generator is an AEX™ handpiece. If incorrect handpiece is being utilized, discard and utilize correct AEX™ disposable handpiece.
	One or more of the saline slots in either of the device electrodes of the handpiece clogged by tissue or coagulated blood.	Clean device electrodes with gauze. Ensure precautions are taken to avoid inadvertent device activation when cleaning device electrode. If this does not correct the problem, return device to Medtronic Advanced Energy and use new device.
	Handpiece pump segment is not inserted into pump head.	Insert pump tubing segment into pump head as shown in User Guide.

Table 6-3. Troubleshooting (continued)

Situation	Possible Cause	Solution
Generator doesn't work	AEX™ Generator damaged.	Contact Biomedical Engineering Department or a Medtronic Advanced Energy representative for assistance. Use a backup AEX™ Generator or traditional techniques to complete the surgical procedure if repairs cannot be made prior to the scheduled surgical procedure.
	AEX™ Generator did not receive a scheduled safety check.	Contact Biomedical Engineering Department or a Medtronic Advanced Energy representative for assistance. Use a backup AEX™ Generator or traditional techniques to complete the surgical procedure if repairs cannot be made prior to the scheduled surgical procedure. See Section 5, *Cleaning and Maintenance,* for maintenance schedule.
	AEX™ Generator plugged into an inappropriate wall outlet (e.g. not protected against ground fault, etc.).	Plug AEX™ Generator into an appropriate wall outlet prior to use.
Unit is on, but did not complete self-test	Software or internal component malfunction.	Turn off, and then turn on the unit. If the fault code reappears: • Record the error code number and refer to *Fault Code Details* in this section. • Use a backup AEX™ Generator or traditional techniques to complete the surgical procedure.
Unit is on and disposable handpiece is activated, but unit does not deliver output	Power setting is too low.	Increase the power. Refer to Section 4, *Operation, Adjusting RF Power Levels.* Use the lowest possible power setting needed to obtain the desired surgical effect.
	Malfunctioning handpiece or improper handpiece connection.	Turn off the unit. Check the device connection. If device continues to malfunction, replace device and contact Medtronic Advanced Energy to report device malfunction.
	A malfunction condition exists.	Check the power display for an error code. Note the code number and refer to *Error Code Details* in this section.
Interference with other device only when the unit is activated	Metal-to-metal sparking.	Check all connections to the unit and handpiece.
	Electrically inconsistent ground wires in the operating room.	Verify that all ground wires are as short as possible and go to the same grounded metal.
Continuous monitor interference	Faulty chassis-to-ground connections.	Check and correct the chassis ground connections for the monitor and for the unit.
	Monitor responding to radiated frequencies.	Check other electrical equipment in the room for defective grounds. If not resolved, contact Biomedical Engineering Department to check with the monitor manufacturer.
Abnormal neuromuscular stimulation *(Stop surgery immediately)*	Metal-to-metal sparking.	Check all connections to the unit and device.

Table 6-3. Troubleshooting (continued)

Situation	Possible Cause	Solution
Ineffective hemostasis	Power setting too low.	Increase the power. Refer to Section 4, *Operation, Adjusting RF Power Levels.* Use the lowest possible power setting needed to obtain the desired surgical effect.
	Tissue under-treated. Tissue not treated long enough to result in a reduction in intraoperative or postoperative blood loss.	See disposable handpiece Instructions For Use and/or device treatment guides for treatment recommendations.
	Wrong fluid used for device irrigation.	Only utilize sterile bag of sodium chloride solution (0.9%NaCl) with the AEX™ System.
	Device electrode(s) of disposable handpiece clogged by tissue or coagulated blood.	Clean device electrodes with gauze. Ensure precautions are taken to avoid inadvertent device activation when cleaning device electrodes. If this does not correct the problem, return device to Medtronic Advanced Energy and use new device.
	Excessive blood, fluid or saline in surgical field where device is being utilized.	Utilize appropriate suction to remove blood, fluid and/or saline. See disposable handpiece Instructions For Use and/or handpiece treatment guides for treatment recommendations.
Unintended tissue effect	Power setting too high.	Decrease the power. Refer to Section 4, *Operation, Adjusting RF Power Levels.*
	Tissue over-treated.	See disposable handpiece Instructions For Use and/or device treatment guides for treatment recommendations.
	Non-AEX™ handpieces utilized.	Ensure device connected to AEX™ Generator is an AEX™ handpiece. If incorrect handpiece is being utilized, discard and utilize correct disposable handpiece.
Excessive saline	Saline flow rate setting too high.	Decrease saline flow rate. Refer to Section 4, *Operation, Adjusting the Saline Flow Rate.*
	Excess saline resulting from priming cycle.	Place the device into a holster or over a container to collect the saline that will exit the device electrodes as a result of the priming process.
	2nd (or more) activation of priming cycle.	Place the device into a holster or over a container to collect the saline that will exit the device electrodes as a result of the priming process.
	Off tissue handpiece activation.	Only activate the disposable handpiece on/over tissue intended to be treated. Activation over another location may result in hot saline run-off onto unintended tissue, patient, patient drapes, hospital staff, and operating room surfaces.
	Saline delivery tubing inserted into pump head instead of pump tubing segment.	Ensure black connector on the disposable pump segment is oriented to the left side of the pump head and the white connector to the right side of the pump head when pump tubing segment is inserted.
	Pump head disengaged following procedure prior to firmly knotting the saline delivery tubing between the drip chamber and the pump segment on the handpiece.	The disposable handpiece and the saline bag will contain unused saline following use of the device. Firmly knot the saline delivery tubing between the drip chamber and the pump segment on the device prior to opening the pump head.
Error codes	Error codes appear.	Turn power off for a minimum of 10 seconds, turn power back on. If error code still displays, contact Medtronic Advanced Energy.

If problem persists after applying the appropriate solution indicated in this table, use a backup AEX™ Generator or traditional techniques to complete the surgical procedure. Contact Medtronic Advanced Energy Customer Service for assistance.

This page intentionally left blank.

7. Specifications

AEX™ Generator

All specifications are nominal and are within ±20% of a stated value at room temperature (77 °F/25 °C) and a nominal input power voltage. All specifications are subject to change without notice.

General

Classification:	IEC 60601-1, Class I
Type:	CF
Internal Design:	Solid state
Output Configuration:	Isolated (RF Floating)
Cooling:	Forced air (fan)
Designed to Meet:	ES60601-1; IEC 60601-1, 60601-1-4, 60601-1-2, 60601-2-2; CAN/CSA C22.2 NO. 601.1.

Dimensions and Weight

Width:	14.5 in (36.8 cm)
Length:	17 in (43.2 cm)
Height:	6.5 in (16.5 cm)
Weight:	<20 lb (9 kg)

Operating Parameters

Temperature:	10 °C to 40 °C
Humidity:	15% to 85% relative humidity, non-condensing

Storage Parameters

Temperature:	–20 °C to 65 °C
Humidity:	0% to 85% Non-condensing relative humidity
Shipping Conditions for Packaged Unit:	–20 °C to 65 °C; 15–85% relative humidity, non-condensing
Atmospheric Pressure:	600 to 795 mmHg (800-1060 hPa)

Audio Specifications

The audio levels stated below are for activation tones (Cut, Coag, and Seal) and error indicator tones (Patient Return Electrode and system alarms) at a distance of one meter. Error indicator tones meet the requirements for IEC 60601-2-2.

	Activation Tone	Error Indicator Tone
Volume:	>43 to 65 dBa, adjustable	>65 dBa, not adjustable
Frequency:	Mono Cut: 1109 Hz Mono Coag: 554 Hz Bipolar Seal: 932 Hz Simultaneous Mono Cut and Bipolar Seal: 330 Hz Simultaneous Mono Coag and Bipolar Seal: 415 Hz	An 8 note sequence alternating between 1865Hz and 1480Hz
Duration:	Continuous while the Generator is activated	¼ second duration for each note, total sequence duration of 2 seconds.

Table 7-1. Mains Input Characteristics

Mains Input Characteristics

Frequency	Mains Voltage (V)			Mains Current (A)	Fuses
Hz	*Nominal*	*Minimum*	*Maximum*	*Maximum*	
50/60	115/230	100	240	8A - 4A	10A

Low Frequency (50/60Hz) Leakage Current

- Earth leakage current in normal condition <5 mA
- Earth leakage current in single-fault condition <10 mA
- Enclosure (touch) leakage current in normal condition <100 µA
- Enclosure (touch) leakage current in single fault condition <500 µA
- Patient leakage current in normal condition <10 µA
- Patient leakage current in single fault condition <50 µA

High Frequency (RF) Leakage Current

- Monopolar RF leakage current <150 mA
- Bipolar RF Leakage Current <100 mA

Table 7-2. Output Characteristics

Output Characteristics

Mode	Power (watts Typical)	Rated Load (ohms)	Maximum Open Circuit Voltage (Vpk)	Operating Frequency (kHz Typical)	Duty Cycle (% Typical)
Low Cut	0.5 to 20	100	1365	469	0.17 to 4.3
Medium Cut	0 to 90	500	585	469	100
High Cut	10 to 50	500	1300	469	37.8 to 66.78
Low Coag	0 to 50	500	1500	469	23.8
High Coag	10 to 50	1000	2600	469	16
Bipolar	20 to 220	100	175 (nom)	469	100

User Duty Cycle

- Cut Mode: 10 seconds ON, 30 seconds OFF
- Coag Mode: 10 seconds ON, 30 seconds OFF
- Bipolar Mode: 40 seconds ON, 80 seconds OFF

Patient Return Electrode Contact Quality Monitor

The system continuously monitors the impedance across the Patient Return Electrode. The system presents audible and visible error indication when it senses a loss of contact quality for the Patient Return Electrode. When the error condition exists, the system deactivates output power.

Single Foil: Once the system establishes the single foil Patient Return Electrode impedance (>18 Ω), an increase of 10 Ω or more will cause a Patient Return Electrode has poor or no connection "E3" error indication. Using a combo device with a monopolar power capability above 50 Watts will cause a Patient Return Electrode Incompatible "E9" error indication.

Split Foil: Once the system establishes the split foil Patient Return Electrode impedance (18 to 135 Ω), an increase greater than 30% or above 135 Ω will cause a Patient Return Electrode has poor or no connection "E3" error indication.

Electromagnetic Compatibility

The AEX™ Generator conforms to electromagnetic compatibility standard EN/IEC 60601-1-2.

Compliance was verified with the following accessories connected to the AEX™ Generator:

Table 7-3. Attached Accessory Cables

Accessory Cable Description	Cable Length (meters)
AC mains power cord	4.6
PlasmaBlade™ device	3.0
Aquamantys™ device	3.2
Patient Return Electrode	2.75
Footswitch receiver	1.2
RS-232 cable	1.8
USB cable	1.8

■ **IMPORTANT:** Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section.

Portable and Mobile RF Communications can affect Medical Electrical Equipment.

Use of the AEX™ Generator is not restricted to specific shielded environments.

Table 7-4. Electromagnetic Emissions

The AEX™ Generator is intended for use in the electromagnetic environment specified below.
The customer or user of the AEX™ Generator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR11	Group 1	● **NOTE:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
RF emissions CISPR11	Class A	The AEX™ Generator is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	▲ **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the AEX™ Generator or shielding the location.
Flicker IEC 61000-3-3	Complies	

Table 7-5. Electromagnetic Immunity

The AEX™ Generator is intended for use in the electromagnetic environment specified below. The customer or user of the AEX™ Generator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
ESD EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 sec.	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles Note 1	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AEX™ Generator requires continued operation during power mains interruptions, it is recommended that the AEX™ Generator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

NOTE 1: The EUT powers down during a 5 second loss of AC Mains power, but recovers into Standby Mode as soon as power is restored. This meets the manufacturer's requirements for maintaining Basic Safety and Risk Management.

Table 7-5. Electromagnetic Immunity (continued)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V/m 150 kHz – 80 MHz	(V1)=3 Vrms	Portable and mobile communications equipment should be separated from the AEX™ Generator by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.5 GHz	(E1)=3 V/m	

Other Specifications

Power Cord:	Generators have a power entry connector to allow connection with a US Hospital Grade power cord or an EU plug power cord. Units accept 100–240 VAC at a frequency of 50/60 Hz, fused at 10 amps.
Display Size:	7 in diagonal (3.5 in tall x 6 in wide)

Output Characteristic Curves

Figure 7-1. Output Power vs Impedance for Low Cut

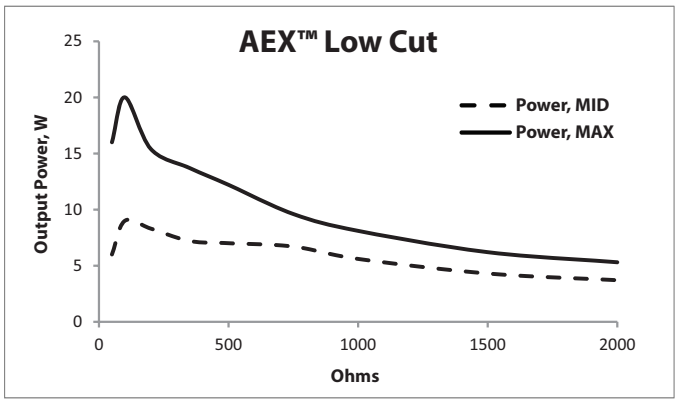


Figure 7-2. Output Power vs Impedance for Medium Cut

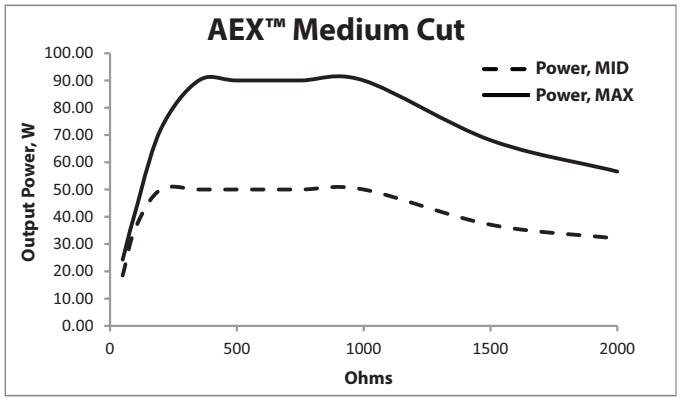


Figure 7-3. Output Power vs Impedance for High Cut

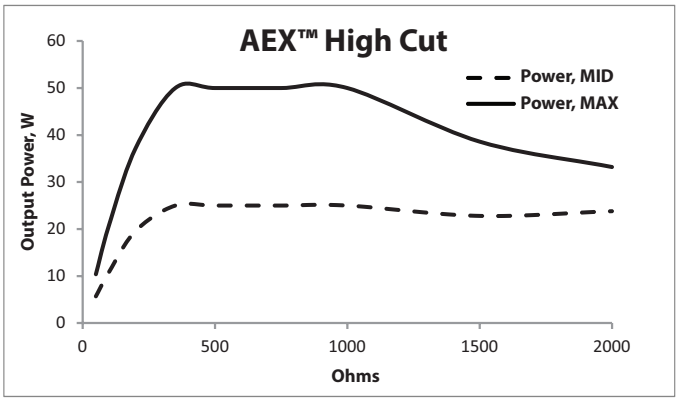


Figure 7-4. Output Power vs Impedance for Low Coag

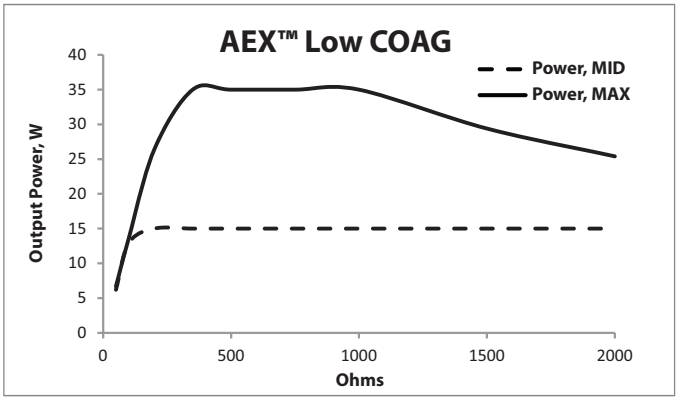


Figure 7-5 Output Power vs Impedance for High Coag

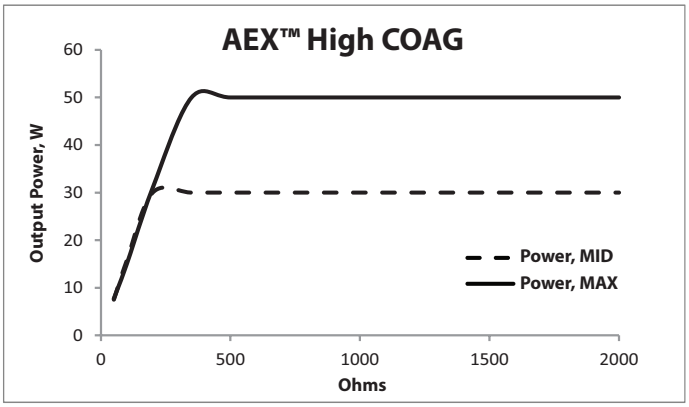


Figure 7-6. Output Power vs Impedance for Bipolar

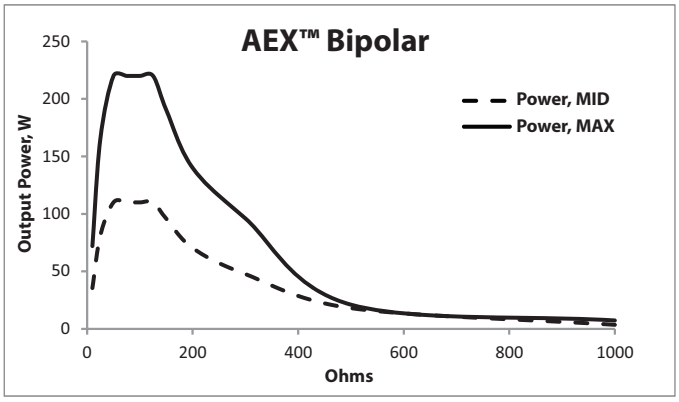
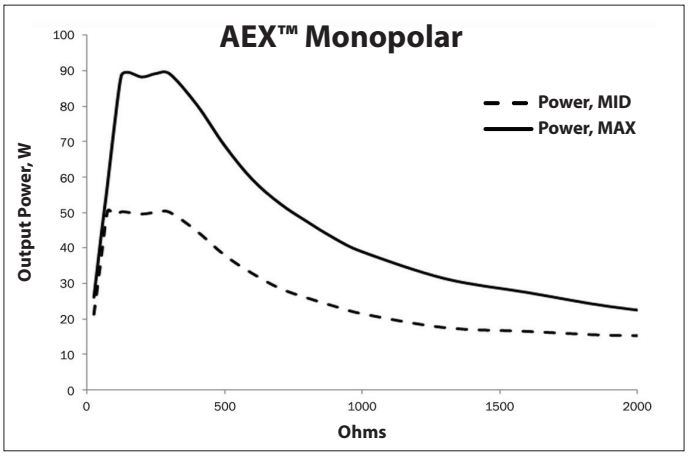


Figure 7-7. Output Power vs Impedance for Monopolar



This page intentionally left blank.

8. Limited Express Warranty and Disclaimers

Limited Express Warranty

Medtronic Advanced Energy LLC warrants the AEX™ Generator against defects in materials or workmanship under normal use and preventive maintenance for the respective warranty periods shown below. Medtronic Advanced Energy will repair or replace the unit without charge, at its option, of any product, or part thereof, which has been returned to Medtronic Advanced Energy LLC or its Distributor within the applicable time period shown below. This warranty does not apply to any product or part that has been adversely affected due to use with devices manufactured or distributed by parties not authorized by Medtronic Advanced Energy LLC; repaired or altered outside Medtronic Advanced Energy's factory; subjected to improper use, negligence or accident or not used in accordance with the instructions provided in this manual. Standard hospital preventive maintenance procedures should be followed and performed by qualified biomedical service personnel and are not covered in the warranty.

- Medtronic Advanced Energy's products are warranted for the following periods after delivery to the original purchaser:
- AEX™ Generator - One (1) Year, Parts and Labor
- AEX™ Wireless Footswitch - One (1) Year, Parts and Labor

Disclaimer of Implied Warranties and Consequential Damages

MEDTRONIC ADVANCED ENERGY LLC MAKES NO OTHER WARRANTIES WITH RESPECT TO THE PRODUCT AND EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER. IN NO EVENT SHALL MEDTRONIC ADVANCED ENERGY LLC BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES OF ANY KIND. THE REMEDIES SET FORTH IN THE LIMITED EXPRESS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE TO CUSTOMER.

This page intentionally left blank.

9. Product Accessories

The following accessories are compatible for use with the AEX™ Generator. Only Medtronic Advanced Energy recommended accessories should be used with the Generator.

- PlasmaBlade™ Monopolar handpieces
- Aquamantys™ Bipolar Disposable handpieces
- PlasmaBlade™ and Aquamantys™ Combination handpieces
- AEX™ Wireless Footswitch
- Standard Patient Return Electrode
    - Single Foil – Valleylab™ Standard PolyHesive™ II E7506 and E7508
    - Split Foil – Adult REM Valleylab™ PolyHesive™ II E7507 and E7509
        - 3M1179 corded adult REM™ pads
- Compatible with Aquamantys™ and AEX™ Carts

This page intentionally left blank.

10. Glossary

This section provides definitions of terms relating to electrosurgery. The information below is provided as a convenience and should not be interpreted as an authoritative discussion of the subject.

active electrode	The device electrode or electrode assembly at which the electrosurgical effect is intended. It usually has a small contact surface area and provides a high current density to achieve the desired surgical effect.
blend	A modified cut waveform incorporating some off-time, thus allowing tissue to cool, and providing varying degrees of hemostasis.
coagulation	The clotting of blood or dehydration of tissue with no cutting effect. Electrosurgical coagulation often incorporates intermittent bursts of high-voltage, low-current electricity.
cutting	Occurs when intense sparks focus the energy and vaporize the tissue. It results from high current density in the tissue causing cellular fluid to burst into steam and disrupt the structure. Voltage is low and current flow is high. In order to induce a cutting effect in human tissue, voltage must exceed 200 Vp.
desiccation	A procedure where a small amount of surface tissue is dried out by placing the active electrode in contact with the tissue. Desiccation differs from fulguration in that peak voltage is lower resulting in the inability of the current to arc through air to tissue. Direct contact between electrode and tissue is required. See fulguration.
disposable accessory	An electrosurgical accessory, such as active electrodes, handles, dispersive electrodes, etc. It is not intended to be used more than once.
duty cycle	The proportion of time (expressed in percentage) that a current or device is on versus off. Duty cycle may be used when referring to current waveforms that are repetitive. Thus high-frequency current would be on using a shorter period of time than a low-frequency current. Duty cycle is also used in reference to electrical components or equipment. For example, some equipment is designed to be used continuously, that is, with a duty cycle rating of 100%, while other equipment may be rated for intermittent use, that is less than 100% duty cycle. Most ESU's are designed to be used intermittently. Typically, they are rated for 25% duty cycles. Use of any equipment beyond its duty cycle rating may result in premature failure.
electrosurgery (surgical diathermy)	The generation and delivery of radio frequency current between an active electrode and a Patient Return Electrode for the purposes of dehydration of tissue. Electrosurgery also includes cutting or vaporizing (tissue explosion). In contrast to electrocautery, the electric current actually passes through the patient.

electrosurgical accessory	Equipment used in conjunction with the electrosurgical generator to accomplish electrosurgery. These include, but are not limited to footswitch, cable, Patient Return Electrode, and active electrode.
fulguration (spray technique)	Coagulating tissue or blood by means of radio frequency electric arcs. In contrast to desiccation, the active electrode is not in good electrical contact with the tissue, and arcs jump from the active electrode to the tissue.
impedance (measured in ohms)	Total opposition, both resistive and reactive, a circuit offers to the flow of alternating current at a given frequency.
mode (operating)	Each of the distinct ways in which the electrosurgical unit can be operated with electrosurgical output, for example, monopolar cutting, monopolar coagulation, monopolar blended, monopolar spray (fulguration).
monopolar	The traditional form of electrosurgical circuit, which uses an active electrode to apply the therapeutic current to the surgical site, and a Patient Return Electrode to return the current to the ESU.
Patient Return Electrode	The electrode at which no electrosurgical effect is intended or desired. It is usually large in area in order to provide a low current density so that no electrosurgical effect occurs at that site. It is also known as a patient plate, patient pad, return pad, plate electrode, return electrode, neutral electrode, dispersive electrode or inactive electrode. It is sometimes (inaccurately) referred to as a grounding plate.
power	The rate at which energy is produced or consumed. Power is equal to voltage multiplied by current, or resistance multiplied by current squared. The unit of measure of power is the watt.
Transcollation	The effect of RF energy applied concurrently with saline resulting in hemostatic sealing and coagulation of soft tissue and bone without charring.

11. Symbols

The following symbols are used on the product and/or packaging.

Table 11-1. Symbols

Symbol	Description
	Defibrillation-proof type CF equipment
	RF Isolated - Patient connections are isolated from earth at high frequency
	**Warning:** Dangerous voltage
	Power ON - To indicate connection to voltage mains
	Power OFF - To indicate disconnection from voltage mains
	UP button - To increase the output level
	DOWN button - To decrease the output level
	Speaker volume control
	Footswitch
	**Caution:** Pinch Hazard - Keep fingers clear of rollers
	To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified personnel.
	Consult instructions for use
	Model number
	Serial number
	Date of manufacture

Table 11-1. Symbols (continued)

Symbol	Description
	Equipotential ground
	**Caution:** Consult accompanying documents
	Non-ionizing radiation
	Explosion risk if used in the presence of flammable anesthetics
	Separate collection of waste at end of life as required by European Directives. Dispose of in accordance with the applicable country regulation.
	In accordance with IEC 60601-1, ES 60601-1, and IEC 60601-2-2; CAN/CSA C22.2 NO. 601.1.
	Manufacturer
	Do not operate in oxygen enriched environments
Rx Only	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.
	Affixed in accordance with European Council Directive 93/42/EEC.
	**Authorized European Representative**
	**Fragile, Handle with Care**
	**Keep Dry**
	**Temperature Limitation**
	**Humidity Limitation**
	**Atmospheric Pressure Limitation**
	**This Way Up**

Medtronic

MEDTRONIC ADVANCED ENERGY LLC
180 International Drive
Portsmouth, NH 03801 USA
+1 866 777 9400

EC REP
Authorized European Representative
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
+31 45 566 8000

Authorized Australian Representative
Medtronic Australasia Pty Ltd.
5 Alma Road
Macquarie Road NSW 2113 Australia

www.medtronicadvancedenergy.com

manuals.medtronic.com

CE 0344

70-10-1455 Rev G
2017/07